UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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JANEEN BRIDA, Individually and as Trustee Ad Litem on behalf of all parties entitled by law to damages in the death of JEROME HEFFNER, SR., Deceased,

Plaintiff,

-against-

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC,

Defendants.

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07 CIV 8060

COMPLAINT

Plaintiff Demands Trial By Jury

Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. Plaintiff, JANEEN BRIDA, as the Trustee Ad Litem on behalf of all parties entitled by law to damages in the death of plaintiff's decedent, JEROME HEFFNER, SR., brings this action under the laws of the State of Pennsylvania, 42 Pa. C.S. §§ 8301 and 8302, to recover damages for personal injuries sustained by, and the wrongful death of, plaintiff's decedent, as the direct and proximate result of defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Neurontin, especially for such "off-label" uses as the treatment of depression, even though Neurontin had not received FDA approval for such use, and at dosages higher than had been approved by the FDA and had been properly tested on humans, even

though the drug had not been tested and studied for such use and had not been found to be safe and effective at any dosage for the treatment of depression.

PARTIES AND JURISDICTION

2. Jurisdiction exists as against the defendants, PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, pursuant to:

(a) 28 U.S.C. Section 1332, in that the plaintiff, JANEEN BRIDA, as Trustee Ad Litem in behalf of all parties entitled by law to damages in the death of plaintiff's decedent, JEROME HEFFNER, SR., is a citizen and resident of the State of Pennsylvania, at the time of his death, plaintiff's decedent, JEROME HEFFNER, SR.., was a citizen and resident of the State of Massachusetts, the defendant, PFIZER INC., is incorporated in business in the State of Delaware and maintains its principal place of business in the State of New York, the defendant, PARKE-DAVIS, is incorporated in the State of Michigan, and maintains its principal place of business in the State of New Jersey, the defendant, WARNER-LAMBERT COMPANY, is incorporated in the State of Delaware and maintains its principal place of business in the State of New Jersey, the defendant, WARNER-LAMBERT COMPANY LLC, is a limited liability company organized under the laws of the State of Delaware, whose sole shareholder and member is the defendant, PFIZER INC., and the amount in controversy exceeds the sum of $75,000.00 exclusive of interest and costs.

(b) 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and all defendants are subject to personal jurisdiction in the Judicial District of the

Southern District of New York and may be deemed to reside in the Southern District of New York.

3. That pursuant to 42 Pa. C.S. § 8301, the plaintiff, JANEEN BRIDA, as the Trustee Ad Litem on behalf of all parties entitled by law to damages in the death of plaintiff's decedent, JEROME HEFFNER, SR., has the right to bring this action, and has brought this action on behalf of herself and any other statutory beneficiaries entitled to recover all damages allowable by law for the wrongful death of her father, JEROME HEFFNER, SR., including, loss of services, companionship, society, affection, guidance, counseling and tutelage as well as the expenses which have been incurred for funeral expenses, medical expenses and the cost of administration. No action has been brought within six months after the death of decedent by the personal representative of decedent and there is no other action pending for the wrongful death of plaintiff's decedent, JEROME HEFFNER, SR.

4. That at the time of plaintiff's decedent death on September 16, 2005, he was survived by his daughter, the plaintiff, JANEEN BRIDA, who resides at 3209 North Hobson Street, Whitehall, Pennsylvania, his son, Jerome Heffner, Jr., who resides at 3693 Pecan, Northampton, Pennsylvania, and his son, John Heffner, who resides at 3693 Pecan, Northampton, Pennsylvania.

5. That at the time of death on September 16, 2005, plaintiff's decedent was then of the age of 66 years and prior thereto, was generally in good health, industrious and possessed of all faculties.

6. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

7. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a foreign corporation authorized to do business in the State of New York.

8. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a business entity actually doing business in the State of New York.

9. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), was and still is a foreign corporation organized under the laws of the State of Michigan.

10. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a foreign corporation authorized to do business in the State of New York.

11. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a business entity actually doing business in the State of New York.

12. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY was and still is a foreign corporation organized under the laws of the State of Delaware.

13. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was and still is a foreign corporation authorized to do business in the State of New York.

14. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was and still is a business entity actually doing business in the State of New York.

15. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY.

16. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY.

17. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company organized under the laws of the State of Delaware.

18. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company authorized to do business in the State of New York.

19. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a business entity actually doing business in the State of New York.

20. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is the sole shareholder and member of the defendant, WARNER-LAMBERT COMPANY LLC.

21. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY LLC.

22. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY LLC.

23. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a division of the defendant, PFIZER INC.

24. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a subsidiary of the defendant, PFIZER INC.

25. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

26. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a division of the defendant, PFIZER INC.

27. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a subsidiary of the defendant, PFIZER INC.

28. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, PARKE-DAVIS.

29. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

30. That on a date prior to September 16, 2005, the defendant, WARNER-LAMBERT COMPANY, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

31. That on a date prior to September 16, 2005, the defendant, WARNER-LAMBERT COMPANY, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

32. That on a date prior to September 16, 2005, the defendant, WARNER-LAMBERT COMPANY, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

33. That on a date prior to September 16, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

34. That on a date prior to September 16, 2005, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY.

35. That on a date prior to September 16, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

36. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

37. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

38. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

39. That on or about December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

40. That on or about December 31, 2002, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

41. That on or prior to December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

42. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

43. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

44. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

45. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

46. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

47. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

48. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

49. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, PARKE-DAVIS.

50. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

51. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY LLC.

52. That on a date prior to September 16, 2005, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, PARKE-DAVIS.

53. That on a date prior to September 16, 2005, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

54. That on a date prior to September 16, 2005, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

55. That on a date prior to September 16, 2005, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

56. That on a date prior to September 16, 2005, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

57. That on a date prior to September 16, 2005, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

58. That on or prior to December 31, 2002, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY LLC.

59. That on or prior to December 31, 2002, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY LLC.

60. That on or prior to December 31, 2002, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant WARNER-LAMBERT COMPANY LLC.

61. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other.

62. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

63. That on or before September 16, 2005, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

64. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other and the defendant, PARKE-DAVIS, became a part of the defendant, PFIZER INC.

65. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, PFIZER INC.

66. That on or prior to December 31, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other and the defendant, WARNER-LAMBERT COMPANY LLC, became a part of the defendant, PFIZER INC.

67. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, consolidated with each other.

68. That on a date prior to September 16, 2005, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

69. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., has its principal place of business in the State of New York.

70. In the year 2000, the defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY, and as the result of that acquisition, the defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, WARNER-LAMBERT COMPANY, which occurred prior to such acquisition.

71. In the year 2000, the defendant, PFIZER INC., acquired the defendant, PARKE-DAVIS, a division of Warner-Lambert Company, and as the result of that acquisition, the defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, PARKE-DAVIS, which occurred prior to such acquisition.

72. On or prior to December 31, 2002, defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY LLC, and pursuant to the terms of and conditions of that acquisition, the defendant, PFIZER INC., is responsible for all acts or

omissions of the defendant, WARNER LAMBERT-COMPANY, LLC, occurring prior to such acquisition.

73. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., presently markets and sells the drug Neurontin.

74. That on a date prior to September 16, 2005, the defendant, PFIZER INC., marketed and sold the drug Neurontin.

75. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

76. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

77. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

78. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

79. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., expects or should reasonably expect its acts to have consequences in

the State of New York, and derives substantial revenue from interstate or international commerce.

80. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, presently markets and sells the drug Neurontin.

81. That on a date prior to September 16, 2005, the defendant, PARKE-DAVIS, marketed and sold the drug Neurontin.

82. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

83. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

84. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

85. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

86. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, expects or should reasonably expect its acts to have consequences in

the State of New York, and derives substantial revenue from interstate or international commerce.

87. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, presently markets and sells the drug Neurontin.

88. That on a date prior to Pensylvania, the defendant, WARNER-LAMBERT COMPANY, marketed and sold the drug Neurontin.

89. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

90. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

91. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

92. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in State of New York.

93. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, expects or should reasonably expect its acts to

have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

94. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, presently markets and sells the drug Neurontin.

95. That on a date prior to September 16, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, marketed and sold the drug Neurontin.

96. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York.

97. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

98. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Pennsylvania.

99. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from good and products consumed in the State of New York.

100. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and

engages in a persistent course of conduct in the State of New York, deriving substantial revenue from interstate commerce.

BACKGROUND

STATEMENT OF THE CASE

101. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq., new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) and (d).

102. However, the FDCA does not prevent doctors from prescribing a drug approved for a particular use for other uses that are different than those approved by the FDA ("off-label" usage).

103. Nonetheless, even though physicians may prescribe drugs for "off-label" usage, the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved. 21 U.S.C. § 331(d).

104. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses or if the manufacturer engages directly or indirectly in marketing or promoting the drug for unapproved uses.

105. Instead, if a manufacturer desires to market and promote the drug for new uses in addition to those already approved, the materials on "off-label" usage must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process for the proposed new use.

106. The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff, from the dangers arising from drugs which, although

approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an "off-label" purpose without adequate study and testing of the drug for such "off-label" usage, and to protect the public, including plaintiff's decedent, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the "off-label" usage of the drug without adequate testing and study of that drug for such "off-label" usage.

107. PARKE-DAVIS, now owned by PFIZER INC., applied for, and in December, 1993, received FDA approval to market and sell Neurontin solely for "adjunctive therapy" in the treatment of certain types of seizures in adult patients suffering from epilepsy, and the FDA approved labeling of Neurontin for that purpose and stated that the drug is only effective at 900 to 1800 milligrams per day.

108. At no time prior to plaintiff's decedent being prescribed Neurontin, did defendants receive FDA approval for any other use of Neurontin except for the above-described treatment of epilepsy or for higher dosages for any purpose, and the FDA never approved the usage of Neurontin at any dosage for the treatment of depression.

109 Commencing in 1995, defendants, as the manufacturer of Neurontin, began to directly and indirectly advertise, market and promote Neurontin for additional "off-label" uses for which FDA approval had not been obtained, including treatment for depression and at higher dosages than had been tested and approved, in violation of the above-described statutory and regulatory system and process, including the FDCA, which prohibits manufacturers from directly or indirectly advertising, marketing and promoting a drug for "off-label" usage, and instead requires that the manufacturer resubmit the drug to the FDA testing and approval process for the

proposed new use and that the materials issued by the manufacturer relating to the proposed new use meet certain stringent requirements.

110. Defendants, as the manufacturer of Neurontin, directly and indirectly advertised, marketed and promoted Neurontin for the treatment of depression and encouraged that higher dosages than those tested be prescribed, even though defendants knew or should have known that there were not adequate tests and studies establishing and confirming that Neurontin was safe and effective for the treatment of depression, and even though defendants knew or should have known that there were no adequate studies showing that Neurontin was safe when prescribed at dosages higher than those approved by the FDA.

111. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of depression even though defendants knew or should have known that Neurontin caused many symptoms or related risk factors associated with suicidal behavior by persons suffering from depression.

112. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of depression even though defendants knew or should have known that Neurontin had no effect in relieving or correcting the symptoms or causes of depression.

113. Defendants' conduct in promoting "off-label" uses of Neurontin for treatment of depression constituted a wanton, callous and reckless disregard of the safety of the public and, in particular of persons suffering from depression.

114. In promoting "off-label" uses of Neurontin, and at higher dosages than approved by the FDA, including treatment of depression, defendants acted without regard to the potential danger and harm to persons for whom the drug was prescribed for the treatment of depression.

115. Defendants actively distributed, sold and placed Neurontin into the stream of commerce and directly and indirectly advertised, marketed and promoted Neurontin as being safe and effective for the treatment of depression and in dosages higher than those approved by the FDA, even though the only approved use of Neurontin at that time was as "adjunctive therapy" for the treatment of epilepsy and even though the FDA had specified a maximum recommended dosage.

116. Neurontin is not reasonably safe and effective for the treatment of persons suffering from depression, and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and defendants' conduct of illegally advertising, marketing and promoting Neurontin for this "off-label" use was unlawful, deceptive and misleading and was in violation of the FDCA.

117. By reason of defendants' conduct of directly and indirectly advertising, marketing and promoting Neurontin for the treatment of depression in an unlawful manner, physicians commenced prescribing Neurontin to their patients diagnosed as suffering from depression, frequently at dosages higher than those approved by the FDA.

118. Upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was indicted in the United States District Court for the District of Massachusetts for violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) and 355, and a copy of such criminal Information is annexed hereto as Exhibit "A" and incorporated into this complaint by reference.

119. Upon information and belief, on or about the 7th day of June, 2004, the defendant, WARNER-LAMBERT COMPANY LLC, formally pled guilty to all charges contained in the Information.

120. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiff's decedent's depression and plaintiff's decedent sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment of depression as prescribed by plaintiff's decedent's physicians.

121. That at all times hereinafter mentioned, plaintiff's decedent was diagnosed by plaintiff's decedent's physician as suffering from depression and was being treated by plaintiff's decedent's physician for such depression.

122. That at all times hereinafter mentioned, upon information and belief, in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin as being safe and effective for the treatment of depression, plaintiff's decedent's physician prescribed Neurontin to treat plaintiff's decedent's depression.

123. That at all times hereinafter mentioned, plaintiff's decedent purchased and consumed Neurontin, as recommended and prescribed by plaintiff's decedent's physician and in the dosages prescribed, in an effort to control the effects of depression.

124. The drug Neurontin was not safe and effective for the treatment of plaintiff's decedent's depression, and plaintiff's decedent sustained injury and harm by reason of plaintiff's decedent's consumption of Neurontin as prescribed by plaintiff's decedent's physician in an effort to treat plaintiff's decedent's depression.

125. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiff's decedent's depression and plaintiff's decedent sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by plaintiff's decedent's physician of such depression.

126. By reason of plaintiff's decedent's consumption of Neurontin in a manner and at a dosage prescribed by plaintiff's decedent's physician in an effort to treat plaintiff's decedent's depression, on September 16, 2005, plaintiff's decedent committed suicide, thereby sustaining severe personal injuries and death.

127. The injuries sustained by plaintiff's decedent were caused by or were contributed to by plaintiff's decedent's consumption of Neurontin at a dosage prescribed by plaintiff's decedent's physician for the treatment of depression in a manner consistent with the direct and indirect advertising, marketing and promoting of this drug for such "off-label" use by defendants.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE DEFENDANTS

128. Plaintiff repeats and reiterates the allegations previously set forth herein.

129. That at all times hereinafter mentioned, defendants were under a duty to exercise reasonable care in the design and development of Neurontin and, in particular, in the advertising, marketing and promoting of Neurontin, both directly and indirectly, to ensure that Neurontin was not used in the treatment of conditions such as depression for which it was not effective and to ensure that Neurontin was not used in a manner or to treat conditions where defendants knew or should have known that the user could sustain injuries and harm from the drug.

130. That defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that defendants, directly and indirectly, advertised, marketed and promoted Neurontin for the treatment of depression, even though Neurontin had not been scientifically determined to be safe

for the treatment of depression and even though Neurontin was, in fact, not reasonably safe for the treatment of depression and furthermore, defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which defendants knew or should have known about.

131. That defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Neurontin even though such drug was not safe or effective for any purpose because it caused or influenced persons using the drug for any purpose to engage in self-destructive behavior including attempting to commit suicide and by failing to adequately warn the public of such risks.

132. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of their marketed drugs, including Neurontin. Defendants continually receive reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Neurontin and defendants' other marketed drugs. Furthermore, defendants continue to conduct clinical trials for their marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to defendants, whether through defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when defendants learn, or should have learned, of new safety information associated with their marketed drugs, they have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor

epidemiology and pharmacovigilance data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

133. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to plaintiff's decedent. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem of suicidality associated with Neurontin use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Neurontin has been on the market in the United States.

134. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Neurontin that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning Neurontin that are the subject of these postmarketing 15-day Alert reports, failing to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

135. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations is evidence of defendants' negligence and constitutes negligence per se.

136. The death of plaintiff's decedent was caused by or was contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiff's decedent, on the part of defendants in

the design, manufacture, distribution, advertising, marketing and promoting of Neurontin as being safe and effective in the treatment of depression and by inducing the public, including plaintiff's decedent, to believe that Neurontin was effective in the treatment of the causes and symptoms of depression.

137. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by defendants was a proximate cause of injuries sustained by plaintiff's decedent.

138. That at all times hereinafter mentioned, plaintiff's decedent did not contribute to plaintiff's decedent's injuries by reason of any negligence or culpable conduct on plaintiff's decedent's part.

139. That as a result of the aforesaid occurrence, the injuries sustained and the death of plaintiff's decedent resulting therefrom, as aforesaid, the beneficiaries of plaintiff's decedent suffered extensive monetary and pecuniary losses and other compensatory damages, and there was also incurred and paid out necessary medical, hospital, funeral and concomitant expenses.

140. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST THE DEFENDANTS

141. Plaintiff repeats and reiterates the allegations previously set forth herein.

142. That at all times hereinafter mentioned, upon information and belief, defendants, by directly and indirectly advertising, marketing and promoting Neurontin for the treatment of depression and by placing this drug in the stream of commerce knowing that Neurontin would be prescribed for the treatment of depression in reliance upon the representations of defendants, expressly warranted to all foreseeable users of this drug, including plaintiff's decedent, that Neurontin was safe and effective for the treatment of depression.

143. That defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Neurontin to all foreseeable users, including plaintiff's decedent, that Neurontin was safe and effective for the purposes for which it had been placed in the stream of commerce by defendants, including for the treatment of depression, and that Neurontin was reasonably safe, proper, merchantable and fit for the intended purpose, including for the treatment of depression.

144. That at all times hereinafter mentioned, plaintiff's decedent relied upon the aforesaid express and implied warranties by defendants.

145. That at all times hereinafter mentioned, plaintiff's decedent's use of Neurontin prior to and up to the time of the above-described incident was consistent with the purposes for which defendants directly and indirectly advertised, marketed and promoted Neurontin, and plaintiff's decedent's use of Neurontin was reasonably contemplated, intended and foreseen by defendants at the time of the distribution and sale of Neurontin by defendants, and, therefore, plaintiff's decedent's use of Neurontin was within the scope of the above-described express and implied warranties.

146. Defendants breached the aforesaid express and implied warranties because Neurontin was not safe and effective for the treatment of depression and because plaintiff's

decedent's use of Neurontin for the treatment of depression caused or contributed to the incident described herein.

147. Plaintiff's decedent gave appropriate notice to defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

148. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A THIRD CAUSE OF ACTION AGAINST THE DEFENDANTS

149. Plaintiff repeats and reiterates the allegations previously set forth herein.

150. That at all times hereinafter mentioned, the drug Neurontin was not suited for the treatment of depression and was not safe and effective for the treatment of depression even though defendants directly and indirectly advertised, marketed and promoted Neurontin for such use.

151. That at all times hereinafter mentioned, the drug Neurontin was not safe and was not suited for the purposes for which defendants, directly and indirectly, advertised, marketed and promoted the drug at the time defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

152. That at all times hereinafter mentioned, upon information and belief, defendants assumed a strict products liability to users and to persons using Neurontin, including plaintiff's decedent, who sustained injuries, harm and damages by reason of the use of Neurontin for

purposes directly and indirectly advertised, marketed, and promoted by defendants, including for the treatment of depression.

153. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST THE DEFENDANTS

154. Plaintiff repeats and reiterates the allegations previously set forth herein.

155. Defendants materially misrepresented material facts concerning the safety and effectiveness of Neurontin in the treatment of depression.

156. Defendants' affirmative misrepresentations include but are not limited to the acts set forth in the following paragraphs.

157. In or about 1993, defendants submitted a new drug application (NDA) for approval of a drug called Neurontin (also known by the chemical name "Gabapentin"), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h)(4) and (5). In that application, defendants sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, the FDA approved Neurontin for that specific use only. Because defendants had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and

efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than that approved use.

158. Commencing in at least June of 1995 and continuing through at least the date of this incident, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD), and migraine headaches, among other uses.

159. Defendants did not file a new NDA seeking FDA approval for any of these unapproved uses at any time prior to the date of this incident.

160. Defendants conducted evaluations of the market potential for certain of the unapproved uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

161. In or about the fall of 1995, defendants' Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including plans for conference calls on pain and a pain consultant meeting.

162. Certain defendants' annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales of the unapproved uses of the drug. The marketing plans budgeted for and funded these tactics.

163. Commencing in early 1995 and continuing at least through the date of this incident, defendants determined not to seek FDA approval for certain unapproved uses.

164. In or about April and May of 1995, defendants performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment, defendants forecast potential revenue from Neurontin for bipolar disorder and anxiety treatment under two scenarios: with and without FDA approval. Defendants' Neurontin Development Team and New Product Committee reviewed the potential uses and concluded that defendants would not seek approval to promote and sell the drug for these unapproved uses.

165. In or about July of 1995, defendants' assessment of Neurontin's market potential for neuropathic pain was distributed to defendants' Neurontin Development Team and to defendants' Vice President for marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to the FDA for approval.

166. One of the principal factors defendants considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that defendants were developing. Defendants expected this new drug would be approved by the FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

167. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in defendants' original NDA approval for Neurontin. If defendants sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those

unapproved uses. Defendants were concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

168. Commencing about June of 1995 until at least the date of this incident, by certain conduct described in greater detail below, defendants promoted the sale and use of Neurontin for certain conditions other than the approved use.

169. In October 1995, a member of defendants' Epilepsy Disease Team circulated a memorandum to a group including other senior members of defendants' Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 of defendants' sales representatives for whom data was available in a two-month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

170. On or about July 10, 1996, defendants' sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

171. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could present lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

172. Defendants employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following

occasions, which are not all-inclusive, defendants' medical liaisons promoted Neurontin for unapproved uses:

(a) In or about June of 1996 defendants' sales representative requested that defendants' medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for unapproved uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of unapproved uses.

(e) After the presentation, defendants' Medical Director praised the event as "another great example of use of the medical liaisons" and an area business manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

173. Defendants organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida, on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to unapproved uses of Neurontin.

174. Defendants invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, defendants paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees.

175. Among the presentations made to the physicians in attendance was one relating to unapproved uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

176. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol and pain.

177. On or about May 8, 1996, following the Jupiter Beach conference, defendants circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations.

178. From August 1-5, 1996, defendants organized an "advisory board meeting," in Atlanta, Georgia, in conjunction with the 1996 Summer Olympics. Defendants expressly instructed several of the physician speakers to address some of the unapproved uses.

179. During that meeting, defendants hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. Defendants already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on defendants' behalf at prior meetings.

180. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

181. On or about March 1, 1996, defendants sponsored a teleconference moderated by defendants' employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

182. In or about May 1996, defendants' Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

183. Defendants hosted dozens of "consultants" meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on "off-label" Neurontin use designed to change the physicians' prescription writing habits. Such consultants' meetings included, but were not limited to the following:

Topic	Location	Dates
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	Feb. 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Feb. 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	Feb. 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Mar. 8-10, 1996
Mastering Epilepsy	Ritz Carlton, Aspen CO	Apr. 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	Apr. 20, 1996
Neurological Consultants (discussed previously)	Jupiter Beach, FL	Apr. 19-21, 1996
Affective Disorder Consultants Conference	Southern Pines, NC	Apr. 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996

Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande, Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	Oct. 18-19, 1996
Non-epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	Sep. 27-28, 1997

Other "consultants" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend these events.

184. Defendants rewarded doctors for their advocacy of Neurontin by paying them honoraria for lending their names to scientific articles which were actually prepared and written by third parties retained by defendants. In 1996, defendants retained AMM/ADELPHI, Ltd. and Medical Education Systems, Inc., to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned "off-label" usage of Neurontin and were generated so that defendants could completely control the publications distributed pursuant to its "publications strategy." The content of these articles were actually written by non-physician technical writers retained by defendants and defendants had the right to control the content of all the articles. Defendants paid all expenses in connection with the creation of these publications.

185. Defendants also founded a speakers' bureau, another method of making large and numerous payments to physicians who recommended Neurontin for "off-label" uses, together

with teleconferences, dinner meetings, consultants meetings, educational seminars, and other events.

186. Defendants utilized medical liaisons who were provided with new company slides that detailed methods to increase "off-label" use of Neurontin, including the following:

Reflex sympathetic dystrophy (RSD)

Peripheral neuropathy

Diabetic neuropathy

Trigeminal neuralgia

Post-herpetic neuralgia

Essential tremor

Restless leg syndrome (RLS)

Attention deficit disorder (ADD)

Periodic limb movement disorder

Migraine

Bipolar disorder

Amyotrophic lateral sclerosis (ALS/Lou Gehrig's Disease)

Drug or alcohol withdrawal seizures

187. The following enumerated misrepresentations, which are not intended to be all-inclusive, relating to "off-label" usage of Neurontin, were routinely made to physicians with the knowledge and consent of marketing personnel of defendants:

a. *Bipolar Disorder.* Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated

ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed.

b. *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes.* Medical liaisons stated that clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Defendants continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin as a safe and effective monotherapy.

c. *Reflex Sympathetic Dystrophy ("RSD").* Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value.

d. *Attention Deficit Disorder ("ADD").* Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim.

e. *Restless Leg Syndrome ("RLS").* RLS was another condition where defendants' medical liaisons were trained to refer to a growing body of date relating to the condition, when no scientific date existed.

f. *Trigeminal Neuralgia.* Although medical liaisons represented that Neurontin could treat trigeminal neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

g. *Post-Herpetic Neuralgia ("PHN").* Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

h. *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD").* Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

i. *Migraine.* Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been such suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by defendants.

j. *Drug and Alcohol Withdrawal Seizures.* Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

188. Defendants sponsored a 1998 study, which was scientifically valid, conducted at the Harvard Research Program, which concluded that patients receiving Neurontin did worse than those on sugar pills, but even though defendants were fully aware of these results from the tests which they sponsored, defendants did not publish the results until two years later after a substantial number of physicians had already been induced to prescribe Neurontin and a substantial number of patients had already been induced to take Neurontin.

189. At each of the presentations known to the plaintiff concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Dr. David Longmire, a participating physician, at the Jupiter Beach Consultants Meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 Consultants Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter, made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Comparable statements were made by another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants Meeting, in May 1996 at the Boston Ritz Carlton Consultants Meeting, and in June 1996 at a Philadelphia Consultants Meeting. Upon information and belief, similar statements were made at all events presented by defendants that discussed Neurontin's use for pain indications. These events include, but are not limited to the following events:

Topic	Date	Location
Neurontin Consultants Meeting	Apr. 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3-4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10-11, 1996	Boston, MA
Advisory Board Meeting	Apr. 14-16, 2000	Grand Wailea Resort Hotel & Spa, Maui, HI
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
New Treatment Options for the Management of Pain: The Role of Anticonvulsants	Apr. 2000	Four Seasons Irving, TX

Advisory Board Meeting	May 26, 2000	Disney Yacht Club Orlando, FL
New Directions in the Understanding and Treatment of Pain	Mar. 24, 2001	Plaza Hotel New York, NY
New Directions in the Understanding and Treatment of Pain	Mar. 2-3, 2001	Hilton Novi Detroit, MI
New Directions in the Understanding and Treatment of Pain	May 4-5, 2001	Westin Galleria Houston, TX
New Directions in the Understanding and Treatment of Pain	Feb. 9-10, 2001	Harbor Court Hotel Baltimore, MD
New Directions in the Understanding and Treatment of Pain	Mar. 9-10, 2001	Fairmont Kansas City Kansas City, MO
New Directions in the Understanding and Treatment of Pain	May 11-12, 2001	Peabody Memphis Memphis, TN
New Directions in the Understanding and Treatment of Pain	Mar. 16-17, 2001	Fairmont San Francisco San Francisco, CA
Advisory Board Meeting	June 16-18, 2000	Westin Resort Hilton Head, SC
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Sheraton Universal City Universal City, CA
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Miami Biltmore Miami, FL
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Ritz Carlton New Orleans New Orleans, LA
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Sheraton Music City Nashville, TN
New Directions in the Understanding and Treatment of Pain	Mar. 30-31, 2001	Ritz Carlton St. Louis St. Louis, MO
New Directions in the Treatment of Neuropathic Pain	Oct. 9-11, 1998	Madeira, Portugal

190. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of restless leg syndrome or RSD. Events presented by defendants that discussed Neurontin's use as a treatment for restless leg syndrome or RSD include, but are not limited to, the following event:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

191. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder. Events presented by defendants that discussed Neurontin's use as a treatment for bipolar disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

192. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by defendants that discussed Neurontin's use as a treatment for social phobia include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA

Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

193. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless, at events

produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by defendants that discussed Neurontin's use as a treatment for panic disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place,New Orleans,LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

194. On September 13, 1996, Parke-Davis submitted a supplemental NDA to approve Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997, because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not make public that its application for monotherapy had been denied. Representative events at which defendants continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Monotherapy Speakers Bureau Meeting	September 1997	La Quinta Resort Palm Springs, CA

195. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and defendants, defendants regularly presented programs in which physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Gabapentin in the Management of Migraine	May 25, 1996	Short Hills, NJ

196. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater than 1800 mg per day, defendants presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day. Defendants' failure to provide this information was a violation of defendants' duties to provide fair and balanced information, and made any prior representations about use of Neurontin at dosages greater than 1800 mg per day false and misleading. In addition to the events identified above, other events where these false and misleading statements were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting on Neurontin	Feb. 4-6, 2000	Royal Sonesta New Orleans, LA
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire, Beverly Hills, CA
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

197. On or about June 29, 2001, the FDA Division of Drug Marketing, Advertising and Communications (DDMAC) advised defendants that through routine monitoring and

surveillance, the DDMAC has identified a slim jim (ID #NSJ5095A1) for Neurontin that is misleading and in violation of the FDCA and applicable regulations, in that this slim jim misleadingly claims improvement in quality of life (QOL) parameters based on the Neurontin Evaluation of Outcomes in Neurological Practice (NEON) study, that among other QOL parameters, the misleading presentation includes improvement in social limitations, memory difficulties, energy level, and work limitations, and that the NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study. difficulties, energy level, and work limitations, and that the NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study.

198. On or about July 1, 2002, the DDMAC advised defendants that through routine monitoring and surveillance, the DDMAC has identified a model (#NE 102254) for Neurontin (gabapentin) that is in violation of the FDCA and applicable regulations because it makes representations about Neurontin which are false or misleading, in that this suggestion of proof of the mechanism of action is false and contrary to the language in the approved product labeling that states "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant action is unknown," and that, furthermore, the full presentation of the areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of central nervous system conditions than has been demonstrated by substantial evidence.

199. From July 1995 through at least August 5, 2002, defendants engaged in a marketing program to promote the use of Neurontin, and to induce physicians to prescribe Neurontin, for medical conditions for which the FDA had not approved Neurontin to be used (i.e., "unapproved" or "off-label" uses). That program included: (a) illegally promoting the sale

and use of Neurontin for a variety of conditions other than the one condition for which its use was approved by the FDA and for which defendants had not performed the required FDA testing or established safety and efficacy, in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.; (b) offering and paying illegal remuneration to doctors, either directly or through third parties, to induce them to promote and prescribe Neurontin for off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b); and (c) making and/or disseminating false statements in presentations and marketing literature sales personnel provided to doctors concerning, among other things, the uses for which the FDA had approved Neurontin, the conditions for which the use of Neurontin was otherwise medically accepted and/or the existence of adequate evidence of the safety and efficacy for such use.

200. In order to avoid sanction and regulation by the FDA, defendants' off-label marketing scheme depended on their concealment of their involvement in off-label promotion of Neurontin, and to make it appear to the public that defendants did not have any hand in any discussions of off-label use. In addition, defendants performed off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles and medical education events. Also, defendants' involvement was hidden because defendants hid their financial connections between the participating physicians and used the vendor participants as payment intermediaries. These activities and others described herein concealed defendants' off-label promotional activities, and plaintiff's decedent could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by defendants.

201. In May 2003, the details of defendants' interactions with the other participants were disclosed through the filing by a former medical liaison, Dr. David Franklin, of previously

sealed materials in opposition to defendants' motion for summary judgment in the qui tam action. This "off-label" promotion scheme remained hidden until, the United States District Court for the District of Massachusetts Court unsealed Dr. Franklin's Amended Complaint in the qui tam case in April or May 2002.

202. In addition, defendants fraudulently concealed information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts.

203. Any applicable statutes of limitation have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff's decedent and other members of the public who were prescribed and ingested Neurontin for off-label uses have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of defendants' conduct, and information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts. Accordingly, defendants are estopped from relying on any statute of limitations to defeat any of plaintiff's claims.

204. Similarly, due to defendants' fraudulent concealment of the aforesaid documents and/or information, the scientific and/or medical community was not apprised of vital information concerning safety and efficacy of the drug Neurontin. Furthermore, due to the aforesaid allegations, plaintiff may rely on the discovery rule in pursuit of this claim.

205. On information and belief, defendants' "off-label" promotion scheme continued after the filing of Dr. Franklin's whistleblower complaint and still continues. For example, through the third quarter of 2002, there were no published scientific studies to support Neurontin's use for a wide variety of diseases that it is being prescribed for including anxiety disorder, attention deficit disorder, bipolar disorder, cluster headache, depression, dosages in excess of 1800 mg per day and many other disorders that physicians are now prescribing Neurontin for that are "off-label." Despite this lack of scientific evidence, Neurontin sales for these and other "off-label" uses have steadily increased, to the point that, according to an article published in the December 1, 2003 issue of Medical Marketing & Media, 90% of Neurontin sales are for "off-label" use. No other drug in the United States has such a high percentage of "off-label" use. The same article estimates that $1.8 billion worth of Neurontin has been sold for "off-label" uses. This increase in sales, and the repeated and increased prescription of Neurontin for "off-label" uses, without any supporting scientific studies that would be prompting such use, cannot be a random event and could not occur without continuing "off-label" promotion by defendants' sales force.

206. As a result of the activities described above, many of which continue to occur after Dr. Franklin filed his whistleblower suit, physicians were inundated with false information about Neurontin. As a result, they continue to prescribe Neurontin for "off-label" uses for which there is no reliable scientific support.

207. On information and belief, Pfizer has a company-wide practice of marketing "off-label" indications. "Off-label" marketing plans exist for Cox 2 inhibitors and, on information and belief, also exist for Neurontin.

208. This continuing course of conduct is evidenced in part by the staggering growth of Neurontin sales for "off-label" uses. Because there are no valid scientific studies supporting such use, a reasonable inference is that the use results from past and continuing promotional efforts by defendants. This clear and unavoidable conclusion follows from observations regarding the ongoing extent of prescriptions written for "off-label" Neurontin use.

209. First, from the perspective of overall Neurontin sales, "off-label" usage of Neurontin has actually increased during the years since 1999; in recent years, "off-label" prescriptions for Neurontin have exceeded 90% of all sales and, in some months, it appears that approved indication usage is negligible.

210. Second, although Neurontin is prescribed for scores of "off-label" indications, since 1999 the types of "off-label" usage continue to be weighted in the precise areas where defendants focused their illegal marketing efforts: bipolar disorder, peripheral neuropathy, migraine, etc.

211. Third, these focus treatment areas of continuing unapproved usage are subject to very intense competition between therapeutic substitutes (other drugs or treatments). Indeed, because manufacturers' incremental cost for drugs in these areas is very small (e.g., only pennies to manufacture an additional pill), manufacturers compete aggressively for market share by spending huge amounts of money for marketing, promotional and sales activities. If any company were to simply pack its tent and discontinue programmatic promotional effort in any therapeutic arena, significant loss of overall sales within that diagnosis regime would certainly occur. For Neurontin, no such dip in overall sales, let alone any significant drop, has occurred.

212. Fourth, Pfizer, like most branded drug companies, monitors the relationship of its sales to its promotional efforts in very short timeframe; Pfizer would be concerned about a drop

in sales within a certain therapeutic regime not after a yearly look-back, or even a quarterly look-back, but over just weeks. The persistent maintenance of high Neurontin sales within multiple, targeted areas for "off-label" promotion over a period of years defies the conclusion that any significant backing away on the marketing, sales or promotion of Neurontin to each of those approved therapeutic areas.

213. For example, sales of Neurontin for the treatment of bipolar disorder have steadily increased since its introduction. This increase is a direct result of defendants' sales representatives recommending to doctors its use for this purpose and their distribution of unapproved promotional materials. These promotional efforts did not stop in 1999, but continued thereafter. There are no valid scientific studies that support Neurontin's use for bipolar disorder. Dr. C. Seth Landefeld has submitted an expert opinion in the Franklin litigation that a review of Drugdex for Neurontin, as of the end of August 2002, reveals "no published scientific studies to support Neurontin's use for . . . bipolar disorder." As a result, tens of thousands of patients who need help and could use other drugs whose effectiveness has been established, were given and are being given Neurontin. These prescriptions for this purpose are still being written and as a direct result of defendants' pre-2000 illegal promotional activities and post-2000 illegal promotional activities.

214. Likewise, sales of Neurontin for pain, ALS, attention deficit disorder, depression and dosages in excess of 1800 mg per day, are also increasing without any scientific evidence supporting use of Neurontin for such indications. Again, as noted by Dr. Landefeld, as of the end of the third quarter of 2002 "there were no published scientific studies to support Neurontin's use for" any of these indications or in an increased dose.

215. Overall, "off-label" sales of Neurontin have steadily increased since 1998, and from 2000 to the present have consistently remained at 93% to 94% of all sales. Actual sales for approved uses have declined. Given the absence of scientific support for such uses, the genesis for those sales can only be past and continuing efforts by defendants to promote "off-label" use.

216. Defendants made additional fraudulent misrepresentations as to the safety and effectiveness of Neurontin, which are not detailed herein but will be determined in discovery.

217. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe and effective in the treatment of depression when, in actuality, Neurontin was ineffective in treating depression and instead influenced users to engage in self-destructive behavior.

218. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe for human consumption in general, when, in actuality, Neurontin influenced users to engage in self-destructive behavior.

219. Defendants knew that Neurontin was not safe and effective in the treatment of depression and that Neurontin was not safe for human consumption in general because such drug influenced users to engage in self-destructive behavior.

220. Defendants knew that physicians, health care providers, and mental health care providers would justifiably rely upon defendants' misrepresentations in prescribing Neurontin in the treatment of depression and in prescribing Neurontin for human consumption in general for the treatment of illnesses and medical and mental conditions and that the public, including persons such as plaintiff's decedent, would justifiably rely upon defendants' misrepresentations in using Neurontin as prescribed by physicians, health care providers and mental health care providers in the treatment of depression and for other prescribed uses.

221. Plaintiff's decedent justifiably relied upon defendants' misrepresentations and, accordingly, consumed Neurontin as prescribed by plaintiff's decedent's physician in the treatment of depression.

222. By reason of plaintiff's decedent's consumption of Neurontin in justifiable reliance upon defendants' fraudulent misrepresentations, plaintiff's decedent sustained injuries and was caused to commit suicide.

223. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE DEFENDANTS

224. Plaintiff repeats and reiterates the allegations previously set forth herein.

225. Defendants acted, used and employed deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Neurontin, at excessively high dosages, for unapproved "off-label" uses, including treatment for depression, to patients/consumers such as plaintiff's decedent, and causing such patients/consumers to purchase, acquire and use Neurontin, at high dosages, for unapproved "off-label" uses, including treatment for depression, as prescribed by

their physicians and medical providers, in connection with the sale and advertisement of the drug Neurontin, in violation of 73 Pa. C.S. § 201-3.

226. By reason of defendants' acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as plaintiff's decedent, were caused to commit suicide.

227. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter, costs and reasonable attorney fees.

AS AND FOR A SIXTH CAUSE OF ACTION AGAINST THE DEFENDANTS

228. Plaintiff repeats and reiterates the allegations previously set forth herein.

229. That at the time of the incident and during plaintiff's decedent's consumption of Neurontin prior to and until the time of his death, plaintiff's decedent suffered suicidal ideations and apprehension of death during a period of time leading up to the actual commission of suicide.

230. That for a period of time leading up to and at the time of the aforesaid suicide, plaintiff's decedent lived and was suffering excruciating mental anguish, severe pain and suffering.

231. That by reason of the facts and premises aforesaid, plaintiff's decedent's survivors entitled to share in the estate sustained damages in a sum which exceeds the jurisdictional limits

of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

WHEREFORE, plaintiff demands judgment against the defendants as follows:

(1) The sum of $100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of $100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of $100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of $100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(5) Actual damages sustained on the Fifth Cause of Action, together with punitive and exemplary damages in an amount to be determined upon the trial of this Action; and

(6) The sum of $100,000,000.00 on the Sixth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon trial of this Action, together with interest, costs and disbursements of this Action.

Dated: September , 2007

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BY: Eleanor L. Polimeni
ELEANOR L. POLIMENI, ESQ.
(EP 8687)

TO: PFIZER INC.
Defendant
235 East 42nd Street
New York, New York

PARKE-DAVIS, a division of
Warner-Lambert Company and
Warner-Lambert Company LLC
Defendant
c/o Pfizer Inc.
235 East 42nd Street
New York, New York

WARNER-LAMBERT COMPANY
Defendant
c/o Pfizer Inc.
235 East 42nd Street
New York, New York

WARNER-LAMBERT COMPANY LLC
Defendant
c/o Pfizer Inc.
235 East 42nd Street
New York, New York

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA Plaintiff, v. WARNER-LAMBERT COMPANY LLC Defendant.	Crim. No. Violations: Title 21, United States Code Sections 331(a), 331(d), 352(f)(1), and 355(a)

INFORMATION

THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS CHARGES THAT:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R.§ 310.3 (h)(4) and (5) . In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)

(Distribution of an Unapproved New Drug)

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)

(Distribution of a Misbranded Drug: Inadequate Directions for Use)

39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

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May 13, 2004